

REMARKS

Claims 15-44 remain in this application. Claims 1-14 are cancelled. Applicants note that the prior filed set of claims contained two claims that were numbered 32. As a result, Applicants have amended the affected claims to renumber the second claim 32 and the subsequent claims as claims 33-38. Applicants apologize for any confusion. Applicant added claims 39-44 to more clearly define the invention, especially that subject matter depicted in Figures 11, 13a, 14a and 15a. In addition, Applicants have amended the specification to more clearly describe that which is shown in Figures 11-15. No new matter has been added.

The Examiner withdrew claims 33-38 from consideration as being distinct and drawn to a non-elected invention. Applicants respectfully traverse this action. Independent claim 33 contains claim elements—a valve and a mounting ring—that are similar to those in originally filed claims 7 and 8, which were elected in this application. While the dependent claims include additional elements, such as a catheter and a guide wire, and have a claim scope that differs from the claim scope sought in claims 15-31, Applicants submit that these claims are allowable on their own merits, but at least because claim 33 is allowable as is discussed in more detail below. As a result, Applicants request that the Examiner reconsider the withdrawal of these claims.

The Examiner rejected claims 15-20 and 30 under 35 U.S.C. § 102(b) as anticipated by Peale (U.S. Patent No. 151,192). While Applicant does not agree with the Examiner's analysis of Peale, as Peale does not disclose a valve for implantation in a mammal, but rather discloses valves for syringes, pumps and other instruments that are "*intended to imitate as nearly as may be, the valves of the arterial, and other portions, of the human organization ...*" (Peale, col 1, lines 10-13), Applicants have amended claim 15 to include language from claim 21 to clarify the claims. Peale does not teach or describe the valve claimed in claim 15: a valve for implantation at a desired location within a mammal that includes a flexible sleeve, at least one cusp configured to permit blood flow through the at least one cusp in a single direction, at least one ring attached to the sleeve, and at least one fastener extending in a direction radially outward with respect to the sleeve. Nor does Peale teach or describe the valve claimed in

dependent claims 16-20 and 30. As a result, Applicants request that the Examiner withdraw the rejection to claims 15-20 and 30, and indicate that new dependent claims 42-44 are allowable.

Further claims 33-41 are clearly novel in view of Peale. Peale does not teach the valve claimed in independent claim 33 or claims 34-41 that depend therefrom. Specifically, Peale does not teach a valve device that includes a mounting ring expandable from a first diameter to a second diameter, and a valve having a proximal end and a distal end, the valve attached to the mounting ring at the proximal end, the valve comprising at least one cusp configured to permit blood flow through the at least one cusp in a single direction. As a result, Applicants seek an indication that claims 33-41 are allowable.

The Examiner rejected claims 20-29 under 35 U.S.C. § 103(a) as being unpatentable over Peale as applied to claim 15, and further in view of Sakura (U.S. Patent No. 4,214,587). Applicant traverses this rejection.

Applicants submit that the Examiner has failed to establish a prima facie case of obviousness. The Federal Circuit has stated the legal test applicable to rejections under 35 U.S.C. § 103(a) as follows:

[V]irtually all [inventions] are combinations of old elements. Therefore an Examiner may often find every element of a claimed invention in the prior art. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be “an illogical and inappropriate process by which to determine patentability.” To prevent the use of hind sight based on the invention to defeat patentability of the invention, this court ***requires the Examiner to show a motivation to combine the references that create the case of obviousness.*** ... To counter this potential weakness in the obviousness construct the suggestion to combine requirements stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

In re Rouffet, 47 USPQ2d 1457-58 (Fed Cir 1998) (citations omitted, emphasis added).

More recently, the Federal Circuit again dealt with what is required to show a motivation to combine references under 35 U.S.C. § 103(a). In this case the court reversed the decision of the Board of Appeals stating:

[R]ather than pointing to specific information in Holiday or Shapiro that suggest the combination..., the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other-in combination with each other... described all of the limitations of the pending claims. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the ... references, nor does the Board make specific-or even inferential-findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any factual findings that might serve to support a proper obviousness analysis.

In re Dembiczak, 50 USPQ2d 1614, 1618 (Fed Cir 1999) (citations omitted).

Thus, from both *In re Rouffet* and *In re Dembiczak* it is clear that the Federal Circuit requires a specific identification of a suggestion, motivation, or teaching why one of ordinary skill in the art would have been motivated to select the references and combine them. The Examiner has not met this burden.

Instead, after describing the alleged teachings of Sakura and Peale, the Examiner states that Sakura “allows for the direct attachment of the valve of Peale to the natural conduit without strict adherence to matching diameters thus alleviating the need for frictional fit,” and concludes that it “would have been obvious to one with ordinary skill in the art to attach the vessel of Peale to the natural conduit via a compressible spring as shown by Sakura”. See page 4 of the Office Action. *In re Rouffet* and *In re Dembiczak* make it clear that this reasoning alone is not enough.

Neither Sakura nor Peale teach or suggest the claimed subject matter of amended claims 15 or 33, nor do they teach the elements of the claims that depend from claims 15 or 33. Sakura discloses an anastomosis device for securing, for example, one blood vessel to another blood vessel. Sakura, col 1:6-10. Sakura does not discuss valves or the affixation of valves anywhere in its specification. On the other hand, as described above, Peale discloses valves *for syringes, pumps and other instruments* that are “intended to imitate as nearly as may be, the valves of the

arterial, and other portions, of the human organization ...” (Peale, col 1, lines 10-13). Peale does not teach a valve designed to be implanted in a mammal. Applicants representative has studied Peale and can find no discussion of how Peale is affixed within the syringes, pumps or other instruments. The Examiner concludes that Peale is affixed with a friction fit. Peale, however, does not identify affixation as an issue. As a result, Applicants see no motivation or suggestion to combine Sakura and Peale, and Applicants request that the Examiner withdraw the rejection.

Further, in addition to being allowable as dependent from either independent claim 15 or 33, dependent claims 16-32 and 34-44 are patentable in their own right. Taking a few examples, neither Sakura nor Peale describe or suggest: a valve that includes a sleeve and a ring attached to the sleeve at the proximal end, as claimed in claim 21; the valve of claim 15, where the ring is attached to the outer surface of the sleeve, as claimed in claim 22; the valve of claim 15, where the fastener includes a series of legs arranged circumferentially about the ring, as claimed in claim 26; the valve of claim 15, where the ring has a longitudinal axis and the fastener includes at least one mounting pin attached to the mounting ring, the mounting pin having two ends offset from one another in the longitudinal direction, as claimed in claim 27; the valve of claim 15, where the two ends of the at least one mounting pin extend radially outward from the mounting ring, as claimed in claim 28; or, the valve of claim 15, wherein the mounting ring is balloon expandable, as claimed in claim 29.

As a result, Applicant requests the Examiner to withdraw the obviousness rejection as to claims 20-29, and to indicate that the remaining claims 30-44 are patentable over this combination.

Finally, the Examiner rejected claim 31 under 35 U.S.C. § 103(a) as being unpatentable over Peale as applied to claim 15, and further in view of Navia (U.S. Patent No. 5,156,621). Applicants traverse this rejection. Claim 31 is patentable at least because it depends from claim 15, which, as described above, is patentable over Peale. As a result, Applicants requests the Examiner to withdraw the rejection.

In connection with this Amendment, Applicants are filing a Request for Continued Examination on this date, along with an Information Disclosure Statement. In addition, Applicants are filing a Petition to Accept an Unintentionally Delayed Claim of Priority under separate cover to the Petitions Office.

Applicants grant the PTO permission to charge the deposit account no. 10-0750/BST/HRT0287 for any fees or charges related to this application. Applicant respectfully requests the Examiner to contact the below-signed if a discussion regarding the merits would advance prosecution of this case.

Respectfully submitted,

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